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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,784	09/15/2000	Malcolm L. Gefter	IMI-044DV3CN	3152

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EXAMINER

EMCH, GREGORY S

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/662,784	GEFTER ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 95,96,102-104 and 111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 95,96,102-104 and 111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claims 95, 96, 102-104 and 111 have been amended as requested in the amendment filed on 11 May 2007. Following the amendment, claims 95, 96, 102-104 and 111 are pending in the instant application.

Claims 95, 96, 102-104 and 111 are under examination in the instant office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Double Patenting

The obviousness-type double patenting rejections of claims 95, 96, 102-104 and 111 as being unpatentable over claims 1-33 of U.S. Patent No. 6,019,972 and over claims 1-24 of U.S. Patent No. 5,547,669 is maintained for reasons of record and as set forth below.

In the reply filed 11 May 2007, Applicants assert that upon indication of allowable claims in the pending application, Applicants will consider submitting a terminal disclaimer, if appropriate.

However, until such a time occurs, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 102-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a polypeptide according to claim 95 with additional limitations. The claims are indefinite because claim 95 is drawn to a composition and not to a polypeptide. Thus, claims 102-104 are improper dependent claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The rejection of claims 95, 96 and 102-104 under 35 U.S.C. 102(b) as being anticipated by Leiterman et al., J. Allergy Clin. Immunol., 74:147-53, 1984, as evidenced by UniProt_03 alignment with accession No. P30440, April 1, 1993 as further evidenced by Harlow & Lane Cold Spring Harbor Labs, 1988, pp. 427 is maintained for reasons of record and as set forth below.

In the reply filed 11 May 2007, Applicants assert that Leiterman fails to disclose any sequence information at all for the cat allergen 1 protein. Accordingly, Applicants assert that Leiterman does not explicitly or inherently teach the amino acid sequence of amino acid residues 3-111 of SEQ ID NO: 6. Applicants allege, "the Examiner appears to rely on the sequence information set forth in UniProt Accession No. P30440, published after the Applicants' priority date, as allegedly disclosing the sequence of the cat allergen 1 protein described in Leiterman. Applicants, however, note that based on the teachings of Leiterman, one of ordinary skill in the art would not have arrived at a

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conclusion that the cat allergen protein 1 of Leiterman necessarily consists of amino acid residues 3-111 of SEQ ID NO: 6." Applicants also allege that "the description of UniProt Accession No. P30440, a copy of which is attached herewith as Appendix A, merely lists Leiterman as one of the references. However, there is nothing in the description, which unequivocally teaches or suggests that the amino acid sequence disclosed therein is necessarily that of the partially-purified cat allergen 1 of Leiterman." Further, Applicant assert that they "have amended the claims such that they are now directed to compositions comprising polypeptides which either comprise the amino acid sequence set forth in SEQ ID NO: 6, polypeptides which are about 30 amino acid residues in length and include amino acid residues 14-39 of SEQ ID NO: 6, or polypeptides consisting of amino acid residues 14-39 of SEQ ID NO: 6. Accordingly, Applicants submit that the foregoing rejection has been rendered moot and respectfully request that this rejection be reconsidered and withdrawn."

Applicants' arguments have been fully considered and are not found persuasive. To clarify, Leiterman et al. explicitly teaches "Cat allergen 1." The reference does not explicitly disclose the sequence information of said protein. However, UniProt Accession No. P30440 teaches the sequence information of the protein of the Leiterman et al. reference, which comprises amino acids 3-111 of Applicants' SEQ ID NO: 6. Thus, the Leiterman et al. reference inherently teaches amino acids 3-111 of Applicants' SEQ ID NO: 6. Applicants' attention is directed to MPEP § 2112 (I), which teaches that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render

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the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.* It is irrelevant that the UniProt accession entry was published after the priority date of the instant application; the entry has been submitted as extrinsic evidence, which demonstrates that a sequence comprising amino acids 3-111 of Applicants' SEQ ID NO: 6 is inherently taught in the *Leiterman et al.* reference. Applicants are reminded that chemical compounds and their properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA1963)).

In addition, Applicants' assertion, "the description of UniProt Accession No. P30440...merely lists *Leiterman* as one of the references...there is nothing in the description, which unequivocally teaches or suggests that the amino acid sequence disclosed therein is necessarily that of the partially-purified cat allergen 1 of *Leiterman*" cannot be accepted without further evidence. MPEP § 2112 (V) teaches that once a product appearing to be substantially identical is made the basis of a rejection, and the

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examiner presents evidence tending to show inherency (in the instant case, sequence alignment A from the office action dated 13 December 2006), the burden of proof shift to Applicant to show an unobvious difference. More specifically, "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). Accordingly, it is the Examiner's position that UniProt Accession No. P30440 teaches the sequence information of the protein of the Leiterman et al. reference, which comprises amino acids 3-111 of Applicants' SEQ ID NO: 6, as evidenced by the sequence alignment of record (referred to above). Applicants' assertion that the Uniprot Accession entry does not teach this is not persuasive based on the evidence of record, and Applicants are reminded that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Furthermore, regarding Applicants' assertions that the claims have been amended "such that they are now directed to compositions comprising polypeptides which either comprise the amino acid sequence set forth in SEQ ID NO: 6, polypeptides which are about 30 amino acid residues in length and include amino acid residues 14-

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39 of SEQ ID NO: 6, or polypeptides consisting of amino acid residues 14-39 of SEQ ID NO: 6," the claims still recite the open language "comprising," which does not exclude additional unrecited elements or method steps (see MPEP § 2111.03). Thus, the instant claims read on peptides comprising the claimed epitope with additional amino acids, such as the protein of the Leiterman et al. reference. Thus as maintained previously, the Leiterman protein anticipates the current claims since it comprises of amino acids 3-111 of Applicants' SEQ ID NO: 6.

Conclusion

No claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Advisory Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
31 July 2007


**LORRAINE SPECTOR
PRIMARY EXAMINER**